

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

OCT 19 2005

PCT

NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)

(PCT Rule 44bis.1(c))

To:

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Docket System

Status Report

Docket Book

entered
USNP

Date of mailing (day/month/year)

13 October 2005 (13.10.2005)

Applicant's or agent's file reference

DEX-0478

IMPORTANT NOTICE

International application No.

PCT/US2004/010039

International filing date (day/month/year)

01 April 2004 (01.04.2004)

Priority date (day/month/year)

01 April 2003 (01.04.2003)

Applicant

DIADEXUS, INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference DEX-0478	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2004/010039	International filing date (<i>day/month/year</i>) 01 April 2004 (01.04.2004)	Priority date (<i>day/month/year</i>) 01 April 2003 (01.04.2003)]
International Patent Classification (IPC) or national classification and IPC 7 C12Q 1/60, 1/00, 1/56, 1/44, G01N 33/53		
Applicant DIADEXUS, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 01 October 2005 (01.10.2005)
Facsimile No. +41 22 740 14 35	Authorized officer <div style="text-align: center; font-weight: bold;">Nora Lindner</div>
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REC'D 27 APR 2005

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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITYTo:
JANE MASSEY LICATA
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) 25 APR 2005

Applicant's or agent's file reference

EX-0478

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US04/10039

International filing date (day/month/year)

01 April 2004 (01.04.2004)

Priority date (day/month/year)

01 April 2003 (01.04.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): C12Q 1/60, 1/00, 1/56, 1/44; G01N 33/53; AG1K 35/34 and US Cl.: 435/11, 4, 13, 19, 975; 424/569

Applicant

DIADEXUS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

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Commissioner for Patents
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Telephone No. 571-272-0700

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/10039

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/10039

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims NONE

YES

Claims 1-35

NO

Inventive step (IS)

Claims NONE

YES

Claims 1-35

NO

Industrial applicability (IA)

Claims 1-35

YES

Claims NONE

NO

2. Citations and explanations:

Claims 1-35 lacks novelty under PCT Article 33(2) as anticipated Packard et al in view of "The Lancet" article.

Packard et al disclose a method for assessing a patient's risk of Coronary Vascular Disease (CVD) by measuring levels of Lipoprotein Associated Phospholipase A2 (Lp-PLA2) and C-reactive protein (CRP). See page 3. Packard et al reported that measuring levels of Lp-PLA2 was a strong predictor of the risk of coronary events. Also, Packard et al reported that measuring levels of CRP in association with other CVD predictors was a strong predictor of the risk of coronary events. See pages 1-3. Packard et al further reported results for patients that smoked and had high blood pressure and LDL cholesterol levels and lower HDL cholesterol levels. See pages 4-7. Packard et al reported results from therapeutic, placebo and healthy control patient studies. Thus, the Packard et al disclosure renders obvious the method for treating a patient and providing a kit as claimed. See pages 1-16. Packard et al does not address using ATP III guidelines for determining patient's risk of CVD.

However, "The Lancet" article reports using ATP III guidelines as a method step in a patient study for evaluating development of coronary vascular disease. See pages 1-2 and pages 19-20.

Claims 1-35 an inventive step under PCT Article 33(3) as being obvious over Packard et al in combination with "The Lancet" article.

Packard et al disclose a method for assessing a patient's risk of Coronary Vascular Disease (CVD) by measuring levels of Lipoprotein Associated Phospholipase A2 (Lp-PLA2) and C-reactive protein (CRP). See page 3. Packard et al reported that measuring levels of Lp-PLA2 was a strong predictor of the risk of coronary events. Also, Packard et al reported that measuring levels of CRP in association with other CVD predictors was a strong predictor of the risk of coronary events. See pages 1-3. Packard et al further reported results for patients that smoked and had high blood pressure and LDL cholesterol levels and lower HDL cholesterol levels. See pages 4-7. Packard et al reported results from therapeutic, placebo and healthy control patient studies. Thus, the Packard et al disclosure renders obvious the method for treating a patient and providing a kit as claimed. See pages 1-16. Packard et al does not address using ATP III guidelines for determining patient's risk of CVD.

However, "The Lancet" article reports using ATP III guidelines as a method step in a patient study for evaluating development of coronary vascular disease. See pages 1-2 and pages 19-20.

Claims 1-35 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.